Remarks

Application Status and Disposition of Claims

In the Final Office Action, the Office considered 1, 2, 5, 6, 9, 10, 14, 17-19, 22, and 25-28, with claims 3, 4, 11-13, 15, 16, 23, and 24 withdrawn from consideration as allegedly directed to a nonelected invention.

With respect to the restriction requirement, Applicants respectfully maintain the position that the restriction requirement is improper. It is unclear exactly on what basis the Examiner maintains the restriction requirement. In the Action, the Examiner states that claims 3 and 4 (for example) "have fine communicating pores open to the inner walls rather than the outer surface." Applicants note that claims 3 and 4 depend from claim 1, so they must, by definition, include the same features as claim 1. If it is the Examiner's position that claim 1 includes features that are not required by claims 3 and 4 (which is strongly suggested by his use of the phrase "rather than the outer surface"), then the Examiner has misinterpreted the claims.

In any event, Applicants allow the withdrawn claims to remain pending, as at least some of these claims are subject to rejoinder. In this regard, as the sole basis for separating some of the pending dependent claims from the claims from which they depend is an allegedly lack of unity, Applicants note that the Examiner will be required to rejoin those dependent claims upon finding allowable the claims from which they depend.

With this paper, no claims are amended, canceled, or added. Thus, claims 1, 2, 5, 6, 9, 10, 14, 17-19, 22, and 25-28 remain pending and under consideration.

Claim Rejections – 35 U.S.C. § 103

The Office Action rejects claims 1, 5, 6, 9, 10, 14, 17, 19, 22, and 25-28 under 35 U.S.C. § 103(a) as allegedly obvious over Smestad (U.S. Patent No. 4,430,760) in view of Trieu et al. (U.S. Patent Application Publication No. 2002/0115742). The Action rejects claims 2 and 18 as allegedly obvious over Smestad in view of Trieu et al. and further in view of Smith et al. (U.S. Patent Application Publication No. 2004/0253279). Applicants respectfully disagree with the rejections for the reasons that follow.

The bone-powder-impregnated structures recited in claims 1 and 17 of the present application can regenerate a large amount of bone from a small amount of bone (page 9, line 28 to page 10, line 3). Because artificial bones or dental roots constituted by the bone-powder-impregnated structures of the present invention have fine communicating pores containing fine bone powder comprising sub-microns particles, functioning as a scaffold for osteoblasts, they have spontaneous bone-forming capability (page 11, lines 20-25).

Smestad discloses a bone prosthesis comprising particulate demineralized bone, dentin, or mixtures thereof, contained within a biocompatible, porous casing. The porous casing is, for example, a pouch or a container made from fabrics or microporous membranes. Smestad teaches that examples for fabrics are woven fabrics such as the Dacron/nylon/carbon composite fabrics, etc., or nonwoven fabrics made of collagen, polyesters, polyamides, or polyolefins, etc., and further, that the microporous membranes are made by forming pores in various kinds of dense polymers such as polycarbonates, polyamides, polyesters, polyolefins, polysaccharides, and cellulosics by well-known pore-forming techniques. Smestad mentions that demineralized bone is made by contacting bone with acid, such as hydrochloric acid, and that the particulate demineralized bone has a particle size in a range of about 40 to 500 μm, preferably 75 to 250 μm (column 2, lines 22-25).

Trieu et al. disclose an orthopedic composition comprising a homogeneous mixture of a biocompatible polymer and a bioactive particulate ceramic having an average particle size of not more than about 500 nm. The ceramic phase can be chosen from a wide variety of ceramics, including synthetic, natural, bioresorbable, or non-resorbable ceramics. For example, the ceramic phase may include bioactive glass and various calcium-containing ceramics, such as calcium phosphate-containing ceramics and including hydroxyapatite, α-tricalcium phosphate, β-tricalcium phosphate, and tetracalcium phosphate.

The Examiner asserts that although Smestad does not disclose the fine bone powder comprises sub-micron particles, it would have been obvious to one of ordinary skill in the art to include the particles in Trieu et al. in a bone prosthesis in Smestad for the purpose of increasing the surface area of the particles to provide for advantageous biological and mechanical properties. Applicants respectfully disagree.

Applicants submit that the particles in Trieu et al. are not obtained by pulverizing living bones and/or teeth, because Trieu et al. specifically mention that use of autograft for the sources of grafts provides several disadvantages, such as availability, the risk of the additional surgery for harvesting the graft, etc., and that use of allograft material does not have the osteoinductive potential of autogenous bone and may thus provide only temporary support (Paragraph [0006] and [0007]). Thus, Applicants submit that Trieu et al. does not teach or suggest the use of a powder obtained by pulverizing living bones and/or teeth for a bioactive particulate ceramic of an orthopedic composition. Accordingly, Trieu et al. neither discloses nor suggests the fine bone powder obtained by pulverizing living bones and/or teeth recited in claims 1 and 17 of the present application.

Applicants also respectfully submit that a person skilled in the art would not combine the Trieu et al. teaching with that of Smestad because the bioactive

particulate ceramic has an average particle size of *not more than* about 500 nm in Trieu et al., whereas the demineralized bone in Smestad must have a particle size in a range of about 40 to 500 μm, preferably 75 to 250 μm (column 2, lines 22-25). Smestad specifically states that the maximum pore size will be less than the minimum particle size of the demineralized bone or dentin powder; accordingly, for embodiments having particle sizes down to 40 microns, the maximum pore size will be below 40 microns (column 3, lines 23-28). Even if the casing lumen having a pore size of 5 microns, which is the *minimum* pore size in Smestad (column 3, lines 30-31), is used for the porous casing in which the bioactive particulate ceramic in Trieu et al. is contained, the bioactive particulate ceramic would leak out, because the ceramic has an average particle size of not more than about 500 nm. Thus, the bioactive particulate ceramic having an average particle size of not more than about 500 nm in Trieu et al. could not be used for the bone prosthesis in Smestad. In other words, use of the Trieu et al.'s particle size in Smestad's composition would render Smestad's composition unsatisfactory for its intended use.

The law clearly states that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants also note that the law states that if the proposed modification of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Thus, Applicants submit that the Office's rejection is legally improper, on at least two legal bases, and respectfully request its withdrawal for at least these reasons.

Applicants further note that features recited in claims 1 and 17 of the present application include that the fine bone powder used in the bone-powder-

impregnated structures is obtained by pulverizing living bones and/or teeth and comprises sub-micron particles. Many fine bone powders comprising sub-micron particles, which can be obtained from a few bone pieces by pulverizing living bones and/or teeth, comprise bone crystals such as calcium phosphate and include fine bone structure having the bone crystals. Thus, the sub-micron particles contained within the fine bone powder are particularly useful for inducing spontaneous formation of bone, because the sub-micron particles being distributed widely in the porous structure form many cores for inducing spontaneous formation of bone. Accordingly, the bone-powder-impregnated structures of the present invention impregnated with fine bone powder comprising sub-micron particles have high bone-forming capability. It is assumed that the bone prosthesis described in Smestad including no sub-micron particles of living bones and/or teeth would have lower bone-inducing capability than that of the present invention.

Although it had been thought that osteoblasts in the bone are destroyed by pulverizing living bones so that the diameters of the bone powder include sub-micron-sized particles, the inventor of the present invention has found that the fine bone powder comprising sub-micron particles is capable of inducing spontaneous formation of bone. The present invention is based on this finding.

In view of the foregoing, Applicants respectfully submit that a person skilled in the art would not have modified the bone prosthesis of Smestad or combined it with the bioactive particulate ceramic of Trieu et al. For at least these reasons, Applicants maintain that independent claims 1 and 17 are novel and nonobvious over Smestad and Trieu et al., and claims 2, 5, 6, 9, 10, 14, 18, 19, 22, 25 and 26 are also patentable over Smestad and Trieu et al., at least because they depend from claims 1 or 17.

With respect to the Examiner's rejection of claims 2 and 18 as being unpatentable over Smestad in view of Trieu et al. and in further view of Smith et

al. (U.S. 2004/0253279), although the Examiner asserts that Smith et al. teaches a porous structure with a density of 1 or more pores per an area of 50 μm x 50 μm, Applicants respectfully disagree. Applicants submit that Smith et al. only the porous article having a porosity of 20% to 95% and comprising cell walls and struts defining pores of pore sizes in the range of 15 to 150 micrometers (paragraph [0023]). Thus, Smith et al. neither disclose nor suggest the fine communicating pores being open on an outer surface of the porous structure at a density of 1 or more pores per an area of 50 μm x 50 μm. Additionally, Smestad, Trieu et al., and Smith et al. do not disclose the bone-powder-impregnated structures comprising a porous or a surface-roughened matrix in claims 1 and 17 of the present application impregnated with the fine bone powder having the diameters including sub-microns obtained by pulverizing living bones.

Accordingly, Applicants respectfully submit that, even if combined, the combination of Smestad, Trieu et al., and Smith et al. would not result in the invention recited in claims 2 or 18. Applicants respectfully submit that claims 2 and 18 are patentable over Smestad, Trieu et al., and Smith et al. and respectfully request withdrawal of the obviousness rejection.

Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the claims. If there are any issues that can be resolved by telephone discussion, Applicants invite the Examiner to contact the undersigned attorney.

Respectfully submitted,
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